pressure increasing agent. Support for these amendments can be found in the specification at, *inter alia*, page 15, lines 12-37, page 19 (table 1), page 21 (table 2), and page 24 (table 3).

The independent claims have also been amended to recited that the embryo induction medium comprises a nitrogen source (rather than specifically reciting casein hydrolysate, NH_4^+, and NO_3^-). Those skilled in the art recognize that casein hydrolysate, NH_4^+, and NO_3^- are nitrogen sources and that any art recognized nitrogen source would serve the same purpose. Accordingly, these amendments to not constitute new matter.

Rejection of Claims 6-37, 39-45, 47-71, 73-96, 98-100, 102-103, 105-106, 108-109, and 110-112 Under 35 U.S.C. §112, first paragraph

Claims 6-37, 39-45, 47-71, 73-96, 98-100, 102-103, 105-106, 108-109, and 110-112 have been rejected under 35 U.S.C. §112, first paragraph. Applicants respectfully traverse the rejection.

The Office Action asserts that the claims are not enabled for transformation methods comprising the use of *Agrobacterium tumefaciens* or electroporation. Regarding the *A. tumefaciens* issue, the Office Action asserts that the transformation of poinsettia resulting in whole transformed plants is unpredictable as evidenced by Follansbee *et al.*, which demonstrated that whole *Euphorbia* cannot be recovered following *A. rhizogenes* transformation. The Office Action asserts that *A. rhizogenes,* as taught by Follansbee, may be manipulated to delete root-inducing genes as taught by Miki *et al.* at page 67-71. Apparently, the Office Action is suggesting that *A. rhizogenes* could be manipulated to become the same or similar to *A. tumefaciens* and, therefore, Follansbee's suggestion that *A. rhizogenes* does not successfully transform whole *Euphorbia* plants would apply equally to *A. tumefaciens*.

However, *A. rhizogenes* and *A. tumefaciens* transformation systems are different and one skilled in the art would not interpret failures of *A. rhizogenes* to mean *A. tumefaciens* would not

function as claimed. Furthermore, Miki does not teach or suggest the manipulation of *A. rhizogenes* to delete the root-inducing genes and neither Follansbee nor Miki disclose the result of transformation of poinsettia using *A. rhizogenes* having deleted root-inducing genes or using *A. tumefaciens*. The Office Action merely speculates that *A. rhizogenes* or *A. rhizogenes* having deleted root-inducing genes would react the same was as *A. tumefaciens*. There is no support for such an assumption in the scientific literature.

Furthermore, while the Office Action cites Follansbee for the teaching of the failure of *A. rhizogenes* transformation methods to support non-enablement, it also relies on Cheetham for its teaching of the successful use of *A. rhizogenes* to allege obviousness. These arguments are not consistent. One cannot on the one hand assert that claims reciting *A. tumefaciens* are not enabled because the prior art demonstrates failure with transfection using *A. rhizogenes* and then at the same time assert teachings employing *A. rhizogenes* renders the claims obvious.

Regarding the electroporation issue, although the applicants traverse the rejection with regard to this method of transformation, solely in an effort to expedite prosecution the claims have been amended to delete electroporation, thereby obviating the rejection.

Rejection of Claims 102-103, 105-106, and 108-109 Under 35 U.S.C. §112, first paragraph

Claims 102-103, 105-106, and 108-109 have been rejected under 35 U.S.C. §112, first paragraph. Applicants respectfully traverse the rejection.

The Office Action asserts that the specification does not provide enablement for claims broadly drawn to the use of any media component for the successful regeneration of whole poinsettia plants. The standard for enablement is whether one skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). The courts have held that one does not look to the claims, but to the specification to find

out how to practice the claimed invention. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 220 U.S.P.Q. 303, 316-17 (Fed. Cir. 1983).

The applicants respectfully submit that specification discloses the exemplified medium components for each claimed media type, and one of skill in the art could make and use the invention with merely routine experimentation commonly employed by those of ordinary skill in the art.

However, in order to advance prosecution, claims 102 and 103 have been amended to recite that the callus induction medium comprises auxin and cytokinin, the embryo induction medium comprises a nitrogen source, and the developmental medium comprises an osmotic pressure increasing agent.

Applicants respectfully request withdrawal of the rejection.

Rejection of Claims 1-3, 97, 101, 104, and 107 Under 35 U.S.C. §102

Claims 1-3, 97, 101, 104, and 107 stand rejected under 35 U.S.C. §102 as anticipated by Lee *et al.* Claim 107 has been canceled; the rejection is therefore moot as it applies to this claim. Applicants respectfully traverse the rejection.

The Office Action asserts that these claims are anticipated by Lee, because Lee teaches each element of the claims. In order for the claims to be anticipated by Lee, Lee must disclose each and every element of the claimed invention. *Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766, 1767 (Fed. Cir. 1988). Lee, however, does not teach or suggest the use of callus induction medium that differs from the embryo induction medium as required by the claims. Further, Lee does not teach or suggest that developmental or maturation media comprise cytokinin and abscisic acid, respectively. These compounds are plant hormones. Rather, Lee teaches that after the embryo induction medium, the embryos are subcultured to hormone free

medium.

Lee teaches:

> [Stem sections of poinsettia] shoot tips were cultured on modified Murashige and Skoog medium containing 1000 mg/L casein hydrolysate, 4.3 μM NAA and 1.8 μM BAP [callus induction medium]. In approximately 4 weeks, the reddish epidermal callus was selected and subcultured back to the same medium [embryo induction medium]. Globular to heart staged embryos . . . were subcultured to hormone free MS medium for further embryo development [maturation medium]. See page 182, left column.

Therefore, Lee does not teach or suggest 1) the use of callus induction medium that differs from the embryo induction medium; 2) the use of a developmental and maturation medium that comprise the hormones cytokinin and abscisic acid, respectively. Therefore, Lee cannot anticipate the claims. Applicants respectfully request withdrawal of the rejection.

Rejection of Claims 6-37, 39-45, 47-71, 73-109, and 110-112 Under 35 U.S.C. §103

Claims 6-37, 39-45, 47-71, 73-109, and 110-112 stand rejected under 35 U.S.C. §103 as obvious over Cheetham *et al.* in view of Miki, Preil, and Nataraja. Claim 107 has been cancelled; the rejection is therefore moot as it applies to this claim. Applicants respectfully traverse the rejection.

The Office Action relies upon Cheetham as a primary reference to demonstrate an Agrobacterium-mediated transformation method of Euphorbia. Cheetham, however, does not teach or suggest an *A. tumefaciens*-mediated transformation method of Euphorbia that results in a poinsettia plant, as recited by the claims. As the Applicants noted in their December 29, 1998, response, Cheetham teaches at page 513 that "no shooting was ever observed" using the disclosed method.

None of the other references provide any teachings that one skilled in the art would have recognized would overcome the failures of Cheetham to obtain whole transgenic poinsettia

plants. Thus, the skilled artisan would not have been motivated to combine the teachings of the other references because there would not have been reasonable expectation of success.

Furthermore, the Applicants' December 1998 Response included an Appendix that contained a statement by one of the authors of Cheetham that despite trying various regimens of hormones to get plant regeneration, it was never achieved. Enclosed herewith is the biography of Pamela J. Weathers, the author of the statement and co-author of Cheetham *et al.*, which identifies Dr. Weathers as being of at least ordinary skill in the art. Thus, this statement, demonstrating failure of others to obtain whole transgenic poinsettia plants, is strong evidence of the non-obviousness of the claims.

The Office Action asserts that Preil suggests the incorporation of poinsettia tissue culture into methods for genetic manipulation of poinsettia at page 49, col. 1, first paragraph. Preil, however, does not teach or suggest the genetic manipulation of poinsettia at all. Rather, Preil only teaches the *in vitro* culture and somatic embryogenesis of poinsettia. Preil does not teach or suggest, alone or in combination, the generation of transgenic poinsettia plants as recited by the claims. Therefore, Preil does not teach or suggest the transformation of poinsettia in any manner.

Several claims recite methods of *in vitro* regeneration of poinsettia plants (sans regeneration). Preil does not teach or suggest the *in vitro* regeneration of poinsettia plants using reddish epidermal callus, an embryo induction medium comprising a nitrogen source, or a developmental medium comprising an osmotic pressure increasing agent, as required by the present claims.

The Office Action asserts Miki teaches Agrobacterium vectors, promoters, selectable marker genes and other genes of interest. Miki, however, does not teach or suggest the use of

these vectors with poinsettia nor provide any teachings of how to overcome Cheetham's inability to regenerate whole transgenic poinsettia plants.

The Office Action asserts that Nataraja teaches the culture of poinsettia embryos and that casein hydrolysate improves callus formation and subsequent plantlet development in poinsettia. Nataraja, however, does not teach or suggest the generation of transgenic poinsettia plants. Nataraja also does not teach or suggest the use of reddish callus as a transformation target. Rather, Nataraja teaches the use or auxin or cytokinin medium but not auxin and cytokinin-containing callus induction medium, see Table 1. Furthermore, Nataraja teaches the use of only one type of medium, while the claims recite the use of more than one type of medium. Therefore, Nataraja cannot teach or suggest an embryo induction medium comprising a nitrogen source or a developmental medium comprising an osmotic pressure increasing agent.

For all of these reasons, the applicants respectfully submit that the claims cannot be obvious over the cited references. Reconsideration and withdrawal of the § 103 rejections is respectfully requested.

The Office Action asserted that the Applicant's statements of unpredictability in obtainment of whole poinsettia plants from tissue culture given the highly genotype-dependant techniques available at the time of the invention and the recalcitrance of transformed Euphorbia cells to produce whole plants is in contrast to the Applicant's argument that the use of *A. tumefaciens* to transform Euphorbia callus tissue is indeed predictable. These two arguments made by the Applicant, the first made in support of unobviousness, and the second made in support of enablement, regard two entirely different predictions. That is, the arguments relate to the predictability of obtaining whole poinsettia plants from tissue culture and the predictability of the ability of an *A. tumefaciens* system to transform poinsettia plants. These two arguments are

in no way inconsistent. The predictability of the use of an *A. tumefaciens* system to transform poinsettia plants is not related to the predictability of obtaining whole poinsettia plants from tissue culture. Transforming poinsettia plants is not the same as obtaining whole plants from tissue culture. Therefore, it is not surprising that predications relating to the two different techniques are different. Each technique must be examined independently to determine predictability.

Applicants respectfully request withdrawal of the rejection.

Rejection of Claims 73-96, 100, 102-103, 105-106, and 108-109 Under 35 U.S.C. §103

Claims 73-96, 100, 102-103, 105-106, and 108-109 stand rejected under 35 U.S.C. §103 as obvious over Miki in view of Preil and Nataraja. Applicants respectfully traverse the rejection.

These same claims were rejected as obvious over Cheetham in view of Miki, Preil and Nataraja as described above. Because this rejection eliminates the Cheetham reference as the primary reference and replaces it with Miki, the arguments presented above apply equally to this rejection. Applicants respectfully request withdrawal of the rejection.

Applicants respectfully request withdrawal of all rejections and a speedy allowance of the claims.

If for any reason the Examiner is unpersuaded by the foregoing, the applicants request a telephonic interview. If there are any questions or comments regarding this Response or application, the Examiner is encouraged to contact the undersigned attorney as indicated below.

Respectfully submitted,

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